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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,417	01/09/2004	Rainer Hammann	P-5917	6382

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EXAMINER

TONGUE, LAKIA J

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/753,417

Applicant(s)

HAMMANN ET AL.

Examiner

Lakia J. Tongue

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on May 1, 2006 is acknowledged. Claims 1-16 are pending and under consideration. Claims 13-16 have been withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejection Withdrawn

1. In view of applicants' response the rejection of claim 1-12 under 35 U.S.C. 103(a) as being unpatentable over Merlino et al in view of Felten et al is withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of detecting antibiotic resistant microorganisms in a sample, comprising a) providing a chromogenic medium, said medium comprising at least one beta-lactam antibiotic, wherein said beta-lactam antibiotic is not oxacillin or methicillin; b) incubating said sample on or in said medium; and c) observing that resistant microorganisms exhibit growth and non-resistant microorganisms do not exhibit growth.

The claims recite in part “wherein said beta-lactam antibiotic is not oxacillin or methicillin”. Applicant has not provided or directed the examiner to where support can be found for the limitation “is not methicillin”. This instantly claimed limitation has not been contemplated in the instant specification.

Moreover, Applicants’ disclosure teaches that in one particular embodiment, the antibiotic towards which the microorganism is resistant is the specific compound methicillin. This teaching does not provide support for the instantly claimed limitation of “is not methicillin”.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-4 and 7-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-8 and 14-16 of copending Application No. 10/528,824. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious over the co-pending claims. The present claim set is drawn to a method of detecting antibiotic resistant microorganisms in a sample comprising a) providing a chromogenic medium, which comprises at least one beta lactam antibiotic, wherein the beta lactam antibiotic is not oxacillin or methicillin, b) incubating the sample on or in the medium and c) observing that the resistant microorganisms exhibit growth and non-resistant microorganisms do not exhibit growth. The copending claims are drawn to a method of detecting methicillin resistant microorganisms in a sample, comprising the steps of: a) inoculating a culture medium comprising an antibiotic and a chromogenic agent with said sample or an inoculum derived from said sample, b) incubating said medium and c) detecting, on said medium, the presence of said methicillin-resistant microorganisms by virtue of the presence of colored colonies. The instant claims are obvious over the co-pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Rambach et al (U.S. 2006/0035309 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-12 are drawn to a method of detecting antibiotic resistant microorganisms in a sample, comprising a) providing a chromogenic medium, said medium comprising at least one beta-lactam antibiotic, wherein said beta-lactam antibiotic is not oxacillin or methicillin; b) incubating said sample on or in said medium;

and c) observing that resistant microorganisms exhibit growth and non-resistant microorganisms do not exhibit growth.

Rambach et al discloses a method for detecting methicillin resistant microorganisms in a sample comprising:

- a) providing a chromogenic medium which has at least one antibiotic chosen from cephalosporins;
- b) inoculating the medium with a sample and incubating the medium; and
- c) detecting the presence of the methicillin-resistant microorganisms (the examiner has interpreted this to meet the limitation of "observing that resistant microorganisms exhibit growth and non-resistant microorganisms do no exhibit growth) (0043-0046 and 0010-0011). Rambach et al discloses that the medium is especially intended for *Staphylococcus aureus* (0009). Moreover, Rambach et al discloses that the media will contain chromogenic agents such as 5-brom-6-chloro-3-indoxyl phosphate and 5-brom-4-chloro-3-indoxyl glucoside (0037). Lastly, Rambach et al discloses that cephalosporin is selected from the group consisting of cefaclor, cefoxitin, cefamandole, cefocinide, ceforanide, ceftazidime, cefoperazone, cefepime, cefpirome and moxalactam among others (0022).

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

5. No claims are allowed.
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Felten et al (Evaluation of three techniques for detection of low level methicillin-resistant *Staphylococcus aureus*: a disk diffusion method with cefoxitin and moxalactam, the vitek 2 system and MRSA-screen latex agglutination test, J. clin. Microbiology, 2002; 40(8): 2766-71).


Merlino et al (New chromogenic identification and detection of *Staphylococcus aureus* and methicillin resistant *S. aureus*, Journal of Clinical Microbiology, 2000; 38(6): 2378-2380).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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